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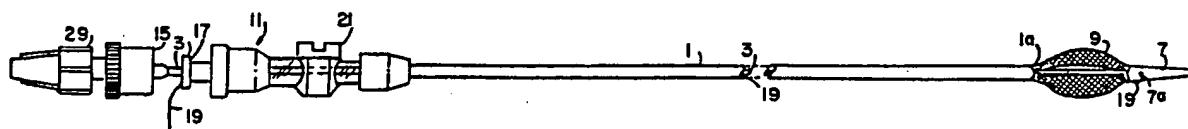
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(71) Applicant: BOSTON SCIENTIFIC CORPORATION [US/US]; 480 Pleasant Street, Watertown, MA 02172 (US).  (72) Inventor: CHU, Michael, S., H. ; 121 Browne Street, Brookline, MS 02146 (US).  (74) Agents: MEEGAN, Owen, J. et al.; 24 North Street, Salem, MA 01970 (US).			Published <i>With international search report.</i> <i>With amended claims.</i>

(54) Title: CATHETER WITH FORAMINOUS ANCHOR



## (57) Abstract

A catheter (1) to be used for the movement of fluids having means (9) for maintaining the position of that catheter (1) within a preselected location in the body. The device comprises an elongated flexible tubular member (1) with a longitudinally extending lumen through it. An axially and radially elastically extensible, foraminous woven tube (9) having two ends is disposed between the end of the tubular member (1a) and a tip (7), the tip (7) being spaced from the tubular member. The foramina of the woven tube (9) allow the free flow of fluid therethrough. The woven tube (9) is translatable between three configurations: relaxed, extended and over-center. In the relaxed configuration the woven tube has a predetermined length and a predetermined diameter, the predetermined diameter which is greater than the outer diameter of the tubular member and preferably an ovoid shape.

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## CATHETER WITH FORAMINOUS ANCHOR

## Background of the Invention

The present invention relates to medical devices and especially to catheters for draining that are to be placed in an organ, duct or vessel of the body for a prolonged period of time. A catheter for draining an organ or vessel can be placed there either subcutaneously (that is by puncturing the skin of the body and directing it through the puncture into the organ) or by inserting the catheter into a natural opening of the body. In many cases, many catheters are removed shortly after they have performed their function and are not kept in place for a long time. On the other hand, some procedures require that the catheters remain in the organ or vessel and with those cases it is necessary to fixedly dispose them so that they will provide for drainage for the desired period. In such cases, the outwardly extending or trailing end of the catheter is usually secured in place by pads and surgical tape. The surgical tape is wrapped around the catheter and attached to the skin to prevent movement or accidental dislodgment therefrom.

According to the present invention, I have discovered that a catheter which is to be disposed in the organ or vessel can be positioned to prevent retrograde movement out of an organ if a multi-shapeable, flexible woven mesh tube formed of plastic strands is disposed between the proximal and distal ends of the catheter. The construction of the woven mesh tube allows it to be translated from a relaxed state in which it has an expanded ovoid configuration to an extended biased configuration in which it has generally cylindrical shape. The extended configuration with the generally cylindrical shape allows the physician to easily place the catheter in the desired

location in the organ to be drained. When in place, the woven tube can be allowed to reshape itself to the relaxed state with its ovoid configuration, thereby maintaining the catheter in place. For further security, the 5 woven tube can be translated into a third configuration in which it assumes an over-center shape, that is it can be urged into a disc or cup-like shape. Either of these over-center shapes can maintain the catheter within the organ or vessel to be drained for a prolonged period of 10 time without adversely affecting the drainage of the organ or vessel or the quantity of fluids that are drained. Also these expanded shapes can be readily translated into the extended configuration so that the physician can withdraw the catheter easily.

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#### Summary of the Prior Art

Catheters that have expandable ends are well known to the art. For example, the United States Patent to Termini, 4,154,242, discloses a catheter that has a self-retainer disposed at the leading end thereof. The retainer includes an array of wings that normally have a cylindrical shape which can be expanded to secure the catheter within an organ to be drained. The wings are formed by a plurality of circumferentially spaced, longitudinally extending slits near the leading end of the catheter. The portions of the tubular member between the slits and intermediate extremities thereof define the wings. When a flexible member disposed in the catheter is retracted, the wings will expand and engage the walls 20 of the organ and retain the catheter in place. I have found, however, that bodily fluids can react with the wings, especially at the ends of the slits, and deteriorate them fairly quickly. When deteriorated, the wings 25 can break off and can become lodged in the organ and damage it. Similarly, the United States patent to Sacks et al., 4,758,219, relates to a winged device in which the 30 35

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wings flex outwardly. These wings enclose part of the drainage area because of their shape and location. Moreover, like the wings of Termenini et al, Sacks et al's wings are also susceptible to corrosion from contact with bodily fluids from the organ being drained.

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Also, it is known to use a dilator catheter in a procedure known as balloon valvuloplasty to treat calcified, stenotic heart valves. In such procedures, a deflated balloon is inserted through a vein or artery and thence into the heart until the balloon is within the heart valve to be treated. The balloon is then inflated to dilate the diseased valve. After dilatation and completion of the procedure, the balloon is deflated and withdrawn from the cardiovascular system of the patient. Such devices are also shown in the United States patent to Shineda et al, 4,819,751, in which a balloon is surrounded with a sheath of woven braid to strengthen it. Patentees, however, are not concerned with the movement of fluids through a catheter and their devices cannot be translated into three configurations.

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The United States patent to Luther, 4,650,466, discloses an angioplasty device formed of a woven tube disposed at the end of a catheter. The woven tube is supported upon a balloon that is inflated to urge against the inner walls of the vascular system. In the United States patent to Gould, 4,572,186, a vessel dilatation device is disclosed which uses a braided cylinder of variable radial size. Achieving variations in the radial size is accomplished by varying the axial length of the braided cylindrical member. The braided cylindrical member is disposed upon an elastomeric material that enhances the smoothness of the outer surfaces of the braided cylinder. Axial compression is used to expand the braid but the expansion is accomplished through a seal system and drainage through a tube is not considered.

### Summary of the Invention

The present invention relates to a medical device and more especially to a catheter that is adapted to be operatively associated with the movement of the fluids in an organ or vessel of the body. Especially, the invention concerns the removal of bodily fluids through a catheter comprising an elongated flexible tubular member with an inner lumen terminating in open proximal and distal ends for the passage of fluids therethrough and in which there is a woven tube disposed preferably near the distal end although it may be disposed anywhere between the ends.

The woven tube is foraminous and axially and radially elastically extensible. It is normally ovoid in shape and has two open ends. The foramina of the wall of the woven tube allow the free and unobstructed flow of fluids therethrough when the catheter is in place and the woven tube is in either the relaxed or over-center configurations. A cannula may be disposed within the catheter and extends to the tip so as to provide a means to translate the woven tube from its normally ovoid shape to a generally cylindrical shape and vice versa. In addition, the woven tube is translatable into a third configuration in which it is over-center. When the woven tube is translated from its relaxed state to the extended configuration, the outer diameter assumes a generally cylindrical shape. In the third configuration, the woven tube is over-center where it can act as a semi-permanent anchor or catheter location maintenance means. In this over-center configuration, the woven tube assumes a disc-like or cup-like shape and cannot be easily dislodged from the organ or vessel that the catheter is draining.

#### Brief Description of the Drawings

Figures 1A, 1B and 1C are side views of one embodiment of the catheter of the present invention, each of the three figures showing different configurations for the woven tube. Figures 1D and 1E are cross-sectional views taken along the lines 1D-1D and 1E-1E, and showing the interior of the catheter;

Figures 2A, 2B and 2C are side elevational views of another embodiment of the present invention, each of the three figures showing different configurations for the woven tube. Figure 2D is an enlarged cross-sectional view of the tip of the catheter showing the disposition of a cannula within the tip;

Figures 3A to 3C and 3E and 3F are elevational views of the catheter of the present invention disposed in an organ for drainage and particularly showing configurations that the woven tube can assume. Figure 3D is a cross sectional view taken along the line 3D-3D of Figure 3E.

#### Description of the Preferred Embodiments

Referring now to Figures 1A to 1E, a catheter 1 is shown. A cannula 3 is disposed inside of the catheter 1 to provide stiffening. Cannula 3 is preferably a stainless steel tube that extends through the entire length of the catheter 1 and engages the interior of a tip 7.

The catheter 1 is a tubular member that usually has a length of at least about 20 centimeters and is formed of a material which provides strength and springiness for operation, yet is soft enough to avoid irritation. Materials that have a desired softness and other necessary characteristics include urethanes, silicones and materials sold under the trademark Percuflex (provided by Meditech, Inc. of Watertown, Massachusetts). The selected material must be biocompatible with and inert to bodily fluids, and optimally must have a softness which

approaches the softness of body tissue to avoid irritation of the tissue within the organ or vessel being drained during the time the device is in place, which may be for ten days and up to several months.

5       The center of the catheter 1 bounded by the catheter's walls, that is the inner lumen, extends from a distal end 1a, that is the end that is intended to be placed into the body, to the proximal end, that is the end which extends from the body.

10      A woven tube 9 such as a expandable braided polyester sleeve manufactured by Schaal Corp., may be disposed adjacent the distal end 1a of the catheter 1. The tube 9 may actually be disposed anywhere between the proximal end and the distal end. The woven tube 9 is preferably thermally bonded around both the outsides of the distal end 1a of the catheter and the tip 7. The woven tube 9 has a radial size that is adjustable by varying the axial length of the tubular member. Variation and axial length is accomplished by moving the tip 7 relative to the distal end 1a of the catheter 1.

15      The woven tube 9 is formed by thin overlapping strands of flexible polyester material, cross-woven over and under each other in generally clock-wise and counter-clockwise directions. The weave is such that a counter clock-wise strand is able to slidably and intersectingly move with respect to a generally clock-wise strand. Also, the braid is such that foramina are formed at the intersections between clock-wise and counter-clockwise strands so as to allow the passage of fluids. The braided strands are formed of a non-brittle polyester material that can withstand and is resilient in response to the compressive forces that are imparted to the woven tube 9 when it has moved from one configuration to another. To form the woven tube into the ovoid shape, a segment of the generally cylindrical woven tube is compressed by exerting pressure upon opposite ends to cause

it to bulge in the middle. When a bulge of the desired diameter is attained, such as shown in Figures 1B or 1C, the woven tube, under compression, is heated to set it at that diameter. Generally, the woven tube can be placed in water at about 100°C for 15 to 30 minutes to set the shape, although exposing it to a stream of hot air at similar temperatures can work also. In the over-center state, the maximum diameter of the woven tube is dependent upon the extended length, diameter and pitch of the woven tube.

Various configurations of the woven tube 9 are shown in Figures 1A, 1B and 1C. The normal or relaxed configuration of the woven tube is a generally ovoid shape, as shown in Figure 1B. In the relaxed configuration, a cannula 3 abuts an axially disposed bore (not shown) disposed within tip 7. Cannula 3 extends through the entire length of catheter 1 and exits through an assembly 11 to terminate in a knob 15, as will be explained later.

In the relaxed configuration shown in Figure 1B, woven tube 9 has an enlarged central diameter and an ovoid shape, that is it has a predetermined diameter which is larger than the diameter of the catheter 1 and preferably 2 to 3 times larger. Woven tube 9 is translatable to an extended configuration with a generally cylindrical shape, as shown in Figure 1A. The generally cylindrical shape enables a physician to insert the catheter into the vessel, duct or organ easily. The extended configuration, shown in Figure 1A, may be accomplished by advancing the cannula 3 distally, and urging locking knob 15 against head 17 and twisting it to engage threads (not shown) disposed inside of locking knob 15.

As shown in Figure 1A, locking knob 15 has been screwed onto head 17, thereby forcing cannula 3 against the interior of tip 7. As tip 7 is moved relative to distal end 1a, woven tube 9 will stretch to form the generally cylindrical shape. In the generally cylindrical

shape, as shown in Figure 1A, the diameter of the woven tube 9 approximates the diameter of the catheter 1 to enable a physician to insert the device in place for drainage.

5       Figure 1C illustrates a third configuration of the woven tube 9. In the drawing, the woven tube 9 is over-center relative to itself, that is it is doubled back on itself. The over-center configuration of the woven tube 9 is produced by withdrawing the cannula 3 from the catheter 1 and then drawing on a suture 19. Suture 19 is threaded between the outside of cannula 3 and the inside of catheter 1. It is attached to a hole 7a that is disposed in the tip 7. Drawing upon suture 19 pulls tip 7 toward distal end 1a and can cause woven tube 9 to double back on itself, as shown. The over-center configuration is a generally cup-like shape, although disc and tulip-like shapes as shown in Figures 3C and 3F, can be formed also, using the same devices to achieve relative movement between tip and the catheter.

10      A way to lock the tubular member 9 in one position is to use a retention lock 21 on assembly 11 as shown in U.S. Patent 4,643,720. Lock 21 includes a barrel 20 which is disposed inside of a cylinder 22. Barrel 20 is rotatable about an axis within cylinder 22. Movement is accomplished by placing a key 24 in keyway 24a. When rotated 180°, a drill hole 20a in barrel 20 can be aligned with a passageway 23a that is disposed within the outer assembly 11 and is normally arranged to receive the cannula 3. When barrel 20 is turned, suture 19 is entrapped between the walls of cylinder 22 and barrel 20 whereby to hold the woven tube 9 in a fixed position.

15      A stylet 27 is used in those situations where it is advantageous to insert the catheter 1 by direct percutaneous puncture. The sharp point of the stylet 27 together with the tip 7 is forced through the skin together with the hollow stiffening cannula 3. In this

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way, the entire assembly of the catheter 1, the cannula 3 and the stylet 27 is introduced percutaneously simultaneously. When the catheter 1 is positioned in an organ, duct or vessel, the stylet 27 and cannula 3 may then be withdrawn. The retention lock 21 may then be twisted to keep sutures 19 in place, after they have been pulled taut to establish the woven tube 9 in its desired configuration.

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The catheter 1 may be introduced into the body over a guidewire, not shown, which guidewire replaces the stylet 27. The catheter 51, shown in Figure 2A, may utilize a guidewire through the cannula 53, the tip 57 being adapted with a narrow bore 58, just wide enough to receive a guidewire, not shown, and not pass the cannula 53 therein.

15

Referring now to Figures 2A to 2D, the catheter 51 is shown. Catheter 51 is similar to the catheter shown in Figures 1A to 1C, and the woven tube 59 is similar also. The tip 57 is different in that it is adapted to detachably receive a tubular cannula 53. As shown in Figure 2D, cannula 53, which in this embodiment may be made from a resilient plastic material, snugly engages an axial bore 57a disposed in the interior of tip 57. The bore 57a extends along the tip's length and tapers with decreasing diameter from the tip to the end. In this way, cannula 53 can wedge into the bore 57a and be held there detachably. An enlargement of the tip is shown in Figure 2D. In this way, cannula 53 can be forced toward the tip 57 so as to shape woven tube 59 into a generally cylindrical shape, as shown in Figure 2A. The relaxed configuration of woven tube 59 is shown in Figure 2B, in which knob 65 is disengaged from head 67. As shown in Figure 2B, cannula 53 is displaced proximally with respect to the catheter 51, leaving woven tube 59 in its relaxed configuration with an ovoid shape. As shown in Figure 2C, when cannula 53 is displaced even further pro-

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ximally from catheter 51, woven tube 59 will assume an over-center configuration, such as described with reference to Figure 1C. Of course, the over-center configuration can be achieved in the embodiment shown in Figures 5 2A to 2C through the use of a taut suture, as discussed previously. In the illustrated embodiment, however, withdrawing the cannula from the catheter can produce the over-center configuration without the sutures. Cannula 10 53 can also be removed from the inside of tip 57 by a twisting withdrawal motion, so as to leave the woven tube 59 in a desired configuration, and so as to free the entire lumen for the withdrawal of bodily fluids that have to be drained or transported, as may be the case when additional openings (not shown) are disposed through 15 the walls of the catheter 51.

As Figures 3A to 3E, various configurations of the woven tube are illustrated (using as examples the Figures 2A to 2C embodiments). In Figure 3A, the catheter 51 is shown entering the organ O to be drained or fluid transferred therefrom through a normal bodily opening T. As 20 can be seen, the woven tube 59 is in the extended configuration and has a generally cylindrical shape with a diameter generally conforming to the diameter of the catheter 51. In Figure 3B, the woven tube 59 is allowed to assume the relaxed configuration with a generally 25 ovoid shape and is shown positioned to allow movement thereof within the organ O. In Figure 3C, the woven tube is shown drawn into a disc-like shape and in Figure 3D and 3E, a cup-like shape is shown. As can be seen especially from Figure 3D, the woven tube 59 is doubled back 30 on itself when it is in the over-center configuration. This configuration is also useful for the withdrawing of stones from a duct or vessel. The foramina, however, are still open and can pass fluids into the lumen of the catheter 51. In the configuration shown in Figure 3F, 35 the woven tube 59 is arranged into a tulip-like shape

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which protectively encloses the tip and which can be used to grasp objects like stones. In each instance, the position of the tube 59 shown in Figures 3B, 3C, 3D and 3E us preferably in the middle of the organ "O", and not adjacent the sidewall thereof, to allow patient movement without injuring those walls.

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It is apparent that modifications and changes can be made within the spirit and scope of the present invention but it is my intention, however, only to be limited by the scope of the appended claims.

As my invention, I claim.

## Claims:

- 1        1. A medical device to be operatively associated  
2              with the movement of fluids in a portion of the body,  
3              said device comprising:
  - 4                  an elongated flexible tubular member having two open  
5                  ends and a longitudinally extending lumen therein, said  
6                  lumen extending to the exterior of said tubular member;
  - 7                  an axially and radially elastically extensible, nor-  
8                  mally ovoid, foraminous woven tube having two ends, said  
9                  woven tube being disposed between the end of said tubular  
10                 member and a tip, said tip being spaced from the end of  
11                 said tubular member, the foramina of said woven tube  
12                 allowing the free flow of fluids therethrough;
  - 13                 means to effect relative movement between said tubu-  
14                 lar member and said tip, whereby to translate said woven  
15                 tube from the normally ovoid shape to a generally cylin-  
16                 drical shape and visa versa.
- 17
- 18        2. The device according to claim 1 wherein the woven  
19              tube is formed of filaments that are braided with strands  
20              wound over and under each other in generally clockwise  
21              and counterclockwise directions such that the clockwise  
22              strands are slidable with respect to the counterclockwise  
23              strands and visa versa.
- 24
- 25        3. The device according to claim 1 wherein the woven  
26              tube encircles the tip and the tubular member to connect  
27              it thereto.
- 28
- 29        4. The medical device according to claim 1 wherein  
30              the means to effect relative movement is a stylet or can-  
31              nula disposed through the lumen and the woven tube and  
32              into the tip.

1       5. The medical device according to claim 4 wherein  
2       the stylet or cannula is detachably fitted into the tip  
3       so that its withdrawal from the tip can cause the woven  
4       tube to be changed from the relaxed configuration to an  
5       over-center configuration.

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7       6. The medical device according to claim 1 wherein  
8       the means to effect relative movement is a suture  
9       attached to said tip and extending through said woven  
10      tube through said lumen to the outside thereof whereby it  
11      can be grasped to change said woven tube from the relaxed  
12      configuration to an over-center configuration.

1           7. A medical device to be operatively associated  
2           with the movement of fluids in a portion of the body,  
3           said device comprising:

4           an elongated flexible tubular member having two open  
5           ends and a longitudinally extending lumen therein, said  
6           lumen extending to the exterior of said tubular member;

7           an axially and radially elastically extensible, for-  
8           aminous woven tube having two ends, said woven tube being  
9           disposed between the end of said tubular member and a  
10          tip, said tip being spaced from said tubular member, the  
11          foramina of said woven tube allowing the free flow of  
12          fluids therethrough, said woven tube being translatable  
13          between a relaxed configuration and an extended configu-  
14          ration, said woven tube, in the relaxed configuration,  
15          having a predetermined length and a predetermined dia-  
16          meter, the predetermined diameter being greater than the  
17          outer diameter of said tubular member, said woven tube in  
18          the extended configuration having a length that is  
19          greater than said predetermined length, and further whe-  
20          rein when in said extended configuration, the outer  
21          diameter of said woven tube can assume a generally cylin-  
22          drical shape, said tip being disposed coaxially with said  
23          tubular member, said tip being movable on said axis away  
24          from said tubular member as said woven tube translates  
25          from the relaxed configuration to the extended configura-  
26          tion, the movement being along the mutual axes of said  
27          tip and said tubular member;

28          means to effect relative movement between said tubu-  
29          lar member and said tip, whereby to translate said woven  
30          tube from the relaxed configuration to the extended con-  
31          figuration and visa versa and thus change its diameter.

1           8. The device according to claim 7 wherein the woven  
2         tube is formed of filaments that are braided with strands  
3         wound over and under each other in generally clockwise  
4         and counterclockwise directions such that the clockwise  
5         strands are slid able with respect to the counterclockwise  
6         strands and visa versa.

7

8           9. The device according to claim 7 wherein the woven  
9         tube encircles the tip and the tubular member to connect  
10         it thereto.

11

12          10. The medical device according to claim 7 wherein  
13         the means to effect relative movement is a stylet or can-  
14         nula disposed through the lumen and the woven tube and  
15         into the tip.

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17          11. The medical device according to claim 10 wherein  
18         the stylet or cannula is detachably fitted into the tip  
19         so that withdrawal of the stylet from the tip can cause  
20         the woven tube to be changed from the relaxed configura-  
21         tion to an over-center configuration.

22

23          12. The medical device according to claim 7 wherein  
24         the means to effect relative movement is a suture  
25         attached to said tip and extending through said woven  
26         tube through said lumen to the proximal end thereof  
27         whereby it can be grasped to change said woven tube from  
28         the relaxed configuration to an over-center configura-  
29         tion.

1           13. A medical device to be operatively associated  
2           with the movement of fluids in a portion of the body,  
3           said device comprising:

4           an elongated flexible tubular member having two open  
5           ends and a longitudinally extending lumen therein, said  
6           lumen extending to the exterior of said tubular member;  
7           an axially and radially elastically extensible, for-  
8           aminous woven tube having two ends, said woven tube being  
9           disposed between the end of said tubular member and a  
10          tip, said tip being spaced from said tubular member, the  
11          foramina of said woven tube allowing the free flow of  
12          fluids therethrough, said woven tube being translatable  
13          between a relaxed configuration, an extended configura-  
14          tion and an over-center configuration, said woven tube in  
15          the relaxed configuration having a predetermined length  
16          and a predetermined diameter, the predetermined diameter  
17          being greater than the outer diameter of said tubular  
18          member, said woven tube in the extended configuration  
19          having a length that is greater than said predetermined  
20          length, and further wherein when in said extended config-  
21          uration, the outer diameter of said woven tube can assume  
22          a generally cylindrical shape, said woven tube in the  
23          over-center configuration having a cup-like shape in  
24          which the walls of the woven tube are doubled over them-  
25          selves, said tip being disposed coaxially with said tubu-  
26          lar member, said tip being movable on said axis away from  
27          said tubular member as said woven tube translates between  
28          the relaxed configuration, the extended configuration,  
29          and the over-center configuration, the movement being  
30          along the mutual axes of said tip and said tubular mem-  
31          ber;

32          means to effect relative movement between said tubu-  
33          lar member and said tip, whereby to translate said woven  
34          tube between the relaxed configuration, the extended con-  
35          figuration and the over-center configuration and visa  
36          versa and thus change its diameter.

1 means to detachably secure said woven tube in the  
2 relaxed configuration and the over-center configuration.  
3

4 14. A catheter to be operatively associated with a  
5 portion of the body, said catheter comprising:

6 an elongated flexible tubular member having a proximal  
7 and a distal end and a longitudinally extending lumen  
8 therein, said lumen extending to the exterior of said  
9 proximal end;

10 an axially and radially elastically extensible, for-  
11 aminous woven tube having two ends, said woven tube being  
12 disposed between the end of said tubular member and a  
13 tip, said tip being spaced from said tubular member, the  
14 foramina of said woven tube being in fluid flow communica-  
15 tion with said inner lumen whereby to provide an opera-  
16 tive association with the body portion, said woven tube  
17 being translatable between a relaxed configuration and an  
18 extended configuration, said woven tube in the relaxed  
19 configuration having a predetermined length and a prede-  
20 termined diameter, the predetermined diameter being  
21 greater than the outer diameter of said tubular member,  
22 said woven tube in the extended configuration having a  
23 length that is greater than said predetermined length,  
24 and further wherein when in said extended configuration,  
25 the outer diameter of said woven tube can approximate the  
26 outer diameter of said tubular member, said tip being  
27 disposed coaxially with said tubular member, said tip  
28 being movable on said axis away from said tubular member  
29 as said woven tube translates from the relaxed configura-  
30 tion to the extended configuration, the movement being  
31 along the mutual axes of said tip and said tubular mem-  
32 ber;

33 means to effect relative movement between said tubu-  
34 lar member and said tip, whereby to translate said woven  
35 tube from its extended configuration to its relaxed con-  
36 figuration and thus increase its diameter, thereby to

1 form a means for curing the catheter in place in the  
2 body and provide full fluid flow communication between  
3 the body and the lumen.

4  
5 15. A catheter for the transfer of body fluids hav-  
6 ing means for maintaining said catheter within a portion  
7 of the body, comprising:

8 a tubular conduit with a lumen therethrough, said  
9 conduit having a proximal end and a distal end;

10 a foraminous woven tube disposed in axial alignment  
11 with said tubular conduit and in fluid communication with  
12 said lumen, said woven tube being distortable to effectu-  
13 ate maintenance of said catheter in the portion of the  
14 body.

15  
16 16. A catheter as recited in claim 15, wherein said  
17 woven tube is disposed in said conduit between said pro-  
18 ximal and distal ends thereof.

19  
20 17. A catheter as recited in claim 16, wherein said  
21 woven tube has an ovoid configuration in its relaxed  
22 state, said ovoid configuration having a larger girth  
23 than the girth of said conduit.

24  
25 18. A catheter as recited in claim 17, wherein said  
26 woven tube has a generally cylindrical configuration in  
27 an extended state, said cylindrical configuration of said  
28 woven tube having generally the same girth as conduit.

29  
30 19. A catheter as recited in claim 18, also includ-  
31 ing means for effectuated said woven tube in its extended  
32 state.

1           20. A catheter as recited in claim 15 wherein said  
2           woven tube is adaptable to configuration in an over-  
3           center state.

4

5           21. A catheter as recited in claim 20, having means  
6           for securing said woven tube in its over-center state.

7

8           22. A catheter as recited in claim 21 wherein said  
9           means for securing said woven tube in its over-center  
10          states comprises a tightenable suture.

11

12          23. A catheter as recited in claim 22 wherein said  
13          means for effectuating said woven tube in its extended  
14          state comprises a rigid stylet disposable through said  
15          lumen and biasable against the distal end of the conduit.

-20-

**AMENDED CLAIMS**

[received by the International Bureau  
on 17 June 1991 (17.06.91);  
original claims 1-23 replaced by amended claims 1-19 (7 pages)]

1. A medical device to be operatively associated with the movement of fluids in a portion of the body, said device comprising:

5       an elongated flexible tubular member (1) having a distal and a proximal end and a longitudinally extending lumen therein;

10      an axially and radially elastically extensible, normally ovoid in its relaxed configuration, foraminous woven tube (9) having two ends, said woven tube (9) being disposed between the distal end of said tubular member (1) and a tip (7), said tip (7) being spaced from the distal end of said tubular member (1), the foramina of said woven tube (7) allowing the free flow of fluids therethrough;

15      means (3) disposed in said lumen to effect relative movement between said tubular member (1) and said tip (7), whereby to translate said woven tube (9) from the normally ovoid shape (Fig. 1B) to a generally cylindrical shape (Fig. 1A) and visa versa.

20      2. The device according to claim 1 wherein the woven tube (9) is formed of filaments that are braided with strands wound over and under each other in generally clockwise and counterclockwise directions such that the clockwise strands are slidable with respect to the counterclockwise strands and visa versa.

25      3. The device according to claim 1 wherein the woven tube (9) encircles the tip (7) and the tubular member (1) to connect it thereto.

30      35     4. The medical device according to claim 1 wherein the means to effect relative movement is a stylet or cannula (3) disposed through the lumen and the woven tube (9) and into the tip (7).

5

5. The medical device according to claim 4 wherein the stylet or cannula (3) is detachably fitted into the tip (7) so that its withdrawal from the tip can cause the woven tube (9) to be changed from the ovoid, relaxed configuration (Fig. 1B) to an over-center configuration (Fig. 1C).

10

6. The medical device according to claim 1 wherein the means to effect relative movement is a suture (19) attached to said tip (7) and extending through said woven tube (9) through said lumen to the outside thereof whereby it can be grasped and pulled to change said woven tube (9) from said normally ovoid, relaxed configuration (Fig. 1B) to an over-center configuration (Fig. 1C).

15

7. A medical device to be operatively associated with the movement of fluids in a portion of the body, said device comprising:

20

an elongated flexible tubular member (1) having a distal and a proximal end and a longitudinally extending lumen therein;

25

an axially and radially elastically extensible, foraminous woven tube (9) having two ends, said woven tube (9) being disposed between the distal end of said tubular member (1) and a tip (7), said tip (7) being spaced from the distal end of said tubular member (1), the foramina of said woven tube (9) allowing the free flow of fluids therethrough, said woven tube (9) being translatable between a relaxed configuration and an extended configuration, said woven tube (9), in the relaxed configuration, having a predetermined length and a predetermined diameter, the predetermined diameter being greater than the outer diameter of said tubular member (1), said woven tube (9) in the extended configuration having a length that is greater than said predetermined length (Fig. 1B), and further wherein when in said extended configuration,

30

35

the outer diameter of said woven tube (9) can assume a generally cylindrical shape (Fig. 1A), said tip (7) being disposed coaxially with said tubular member (1), said tip (7) being movable on said axis away from the distal end 5 of said tubular member (1) as said woven tube (9) translates from the relaxed configuration to the extended configuration (Fig. 1B), the movement being along the mutual axes of said tip (7) and said tubular member (1);

means (3) disposed within said lumen to effect relative movement between the distal end of said tubular member (1) and said tip (7), whereby to translate said woven tube (9) from the relaxed configuration (Fig. 1B) to the extended configuration (Fig. 1A) and visa versa and thus change its diameter.

15

8. The device according to claim 7 wherein the woven tube (9) is formed of filaments that are braided with strands wound over and under each other in generally clockwise and counterclockwise directions such that the clockwise strands are slidable with respect to the counterclockwise strands and visa versa.

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9. The device according to claim 7 wherein the woven tube (9) encircles the tip (7) and the tubular member (1) to connect it thereto.

30

10. The medical device according to claim 7 wherein the means (3) to effect relative movement is a stylet or cannula disposed through the lumen and the woven tube (9) and into the tip (7).

35

11. The medical device according to claim 10 wherein the stylet or cannula (3) is detachably fitted into the tip (7) so that withdrawal of the stylet (3) from the tip (7) can cause the woven tube (9) to be changed from the relaxed configuration to an over-center configuration.

5

12. The medical device according to claim 7 wherein the means to effect relative movement is a suture (19) attached to said tip (7) and extending through said woven tube (9) through said lumen to the proximal end thereof whereby it can be grasped and pulled to change said woven tube (9) from the relaxed configuration (Fig. 1B) to an over-center configuration (Fig. 1C).

10

13. A medical device to be operatively associated with the movement of fluids in a portion of the body, said device comprising:

an elongated flexible tubular member (1) having a distal and a proximal end and a longitudinally extending lumen therein;

15

an axially and radially elastically extensible, foraminous woven tube (9) having two ends, said woven tube being disposed between the distal end of said tubular member (1) and a tip (7), said tip (7) being spaced from the distal end of said tubular member (1), the foramina of said woven tube (9) allowing the free flow of fluids therethrough, said woven tube (9) being translatable between a relaxed configuration (Fig. 1B), an extended configuration (Fig. 1A) and an over-center configuration (Fig. 1C), said woven tube (9) in the relaxed configuration having a predetermined length and a predetermined diameter, the predetermined diameter being greater than the outer diameter of said tubular member (1), said woven tube (9) in the extended configuration having a length that is greater than said predetermined length, and further wherein when in said extended configuration, the outer diameter of said woven tube (9) can assume a generally cylindrical shape, said woven tube (9) in the over-center configuration having a cup-like shape in which the walls of the woven tube (9) are doubled over themselves, said tip being disposed coaxially with said tubular member (1), said tip (7) being movable on said axis away

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from said tubular member (1) as said woven tube (9) translates between the relaxed configuration, the extended configuration, and the over-center configuration, the movement being along the mutual axes of said tip (7) and said tubular member (1);

means disposed within said lumen to effect relative movement between the distal end of said tubular member (1) and said tip (7), whereby to translate said woven tube (9) between the relaxed configuration, the extended configuration and the over-center configuration and visa versa and thus change its diameter.

means to detachably secure said woven tube (9) in the relaxed configuration and the over-center configuration.

14. A catheter to be operatively associated with a portion of the body, said catheter comprising:

an elongated flexible tubular member (1) having a proximal and a distal end and a longitudinally extending lumen therein;

an axially and radially elastically extensible, foraminous woven tube (9) having two ends, said woven tube (9) being disposed between the distal end of said tubular member (1) and a tip (7), said tip (7) being spaced from the distal end of said tubular member (1), the foramina of said woven tube (9) being in fluid flow communication with said lumen whereby to provide an operative association with the body portion, said woven tube (9) being translatable between a relaxed configuration and an extended configuration, said woven tube (9) in the relaxed configuration having a predetermined length and a predetermined diameter, the predetermined diameter being greater than the outer diameter of said tubular member (1), said woven tube (9) in the extended configuration having a length that is greater than said predetermined length, and further wherein when in said extended configuration, the outer diameter of said woven tube (9) can

approximate the outer diameter of said tubular member (1), said tip (7) being disposed coaxially with said tubular member (1), said tip (7) being movable on said axis away from said tubular member (1) as said woven tube (9) translates from the relaxed configuration to the extended configuration, the movement being along the mutual axes of said tip (7) and said tubular member (1);  
5 means (3) disposed within said lumen to effect relative movement between said tubular member (1) and said tip (7), whereby to translate said woven tube (9) from its extended configuration to its relaxed configuration and thus increase its diameter, thereby to form a means for securing the catheter in place in the body and provide full fluid flow communication between the body and the lumen.  
10  
15

15. A drainage catheter for the transfer of bodily fluids having means for maintaining said catheter within a portion of the body, comprising:

20 a tubular conduit (1) with a proximal and a distal end and a lumen therein;  
a foraminous woven tube (9) disposed in axial alignment with said tubular conduit (1) and in fluid communication with said lumen, the foramina of said woven tube (9) allowing the free flow of fluids therethrough said foraminous tube (9) having an ovoid shape in its relaxed configuration;  
25 means (3) disposed in said lumen to increase the diameter of said woven tube (9) to effectuate disposition and maintenance of said catheter in said portion of the body.  
30

35 16. A catheter as recited in claim 15 wherein said woven tube (9) is configurable in an over-center configuration.

17. A catheter as recited in claim 16 further including means disposed at the proximal end of said tubular conduit (1) for securing said woven tube (9) in its over-center configuration.

5

18. A catheter as recited in claim 17 wherein said means for securing said woven tube in its over-center configuration comprises a tightenable suture (19).

10

19. A drainage catheter for the transfer of bodily fluids having means for maintaining said catheter within a portion of the body, comprising:

a tubular conduit (1) with a proximal and a distal end and with a lumen therein;

15

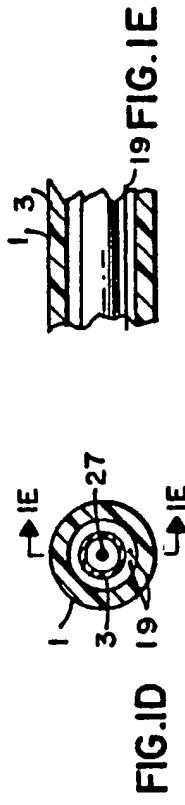
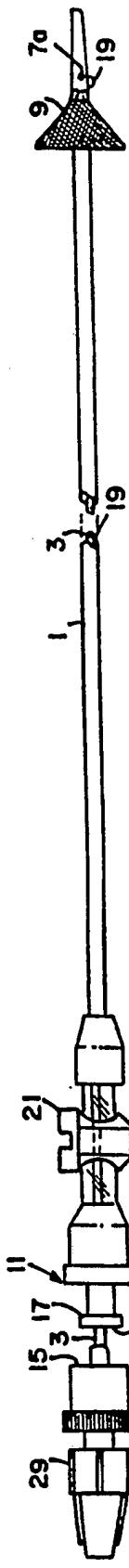
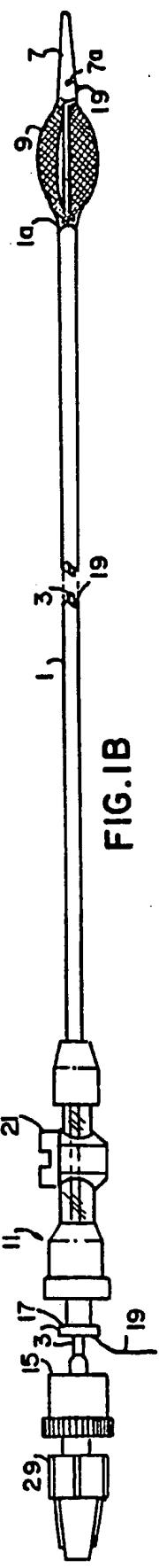
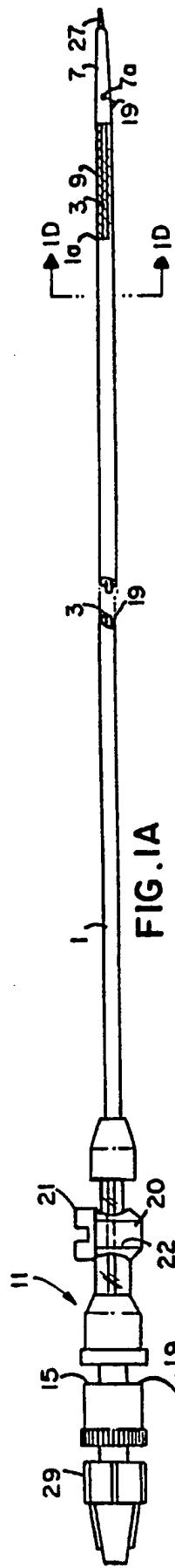
a foraminous woven tube (9) disposed at the distal end of said tubular conduit (1) in axial alignment with said tubular conduit and in fluid communication with said lumen, the foramina of said woven tube (9) allowing the free flow of fluids therethrough, said foraminous tube having an ovoid configuration in its relaxed configuration, said ovoid configuration having a larger girth than the girth of said conduit (1);

20

means (3) disposed in said lumen to increase the diameter of said woven tube to effectuate disposition and maintenance of said catheter in said portion of the body.

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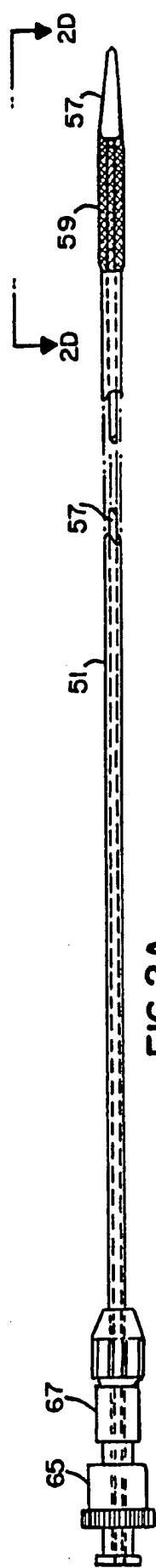


FIG. 2A

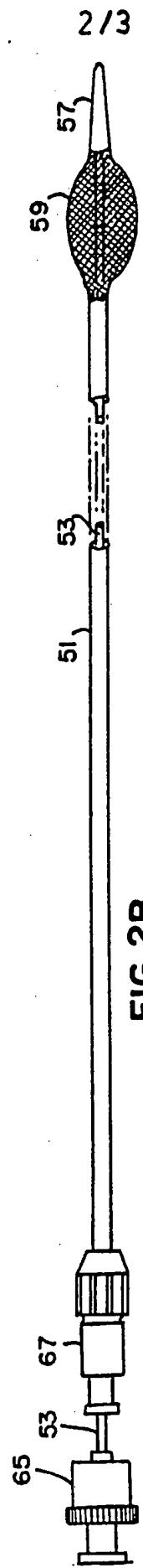


FIG. 2B

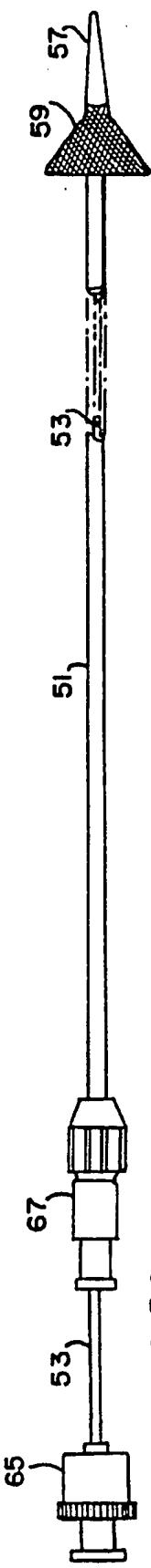


FIG. 2C

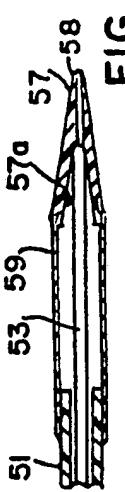


FIG. 2D

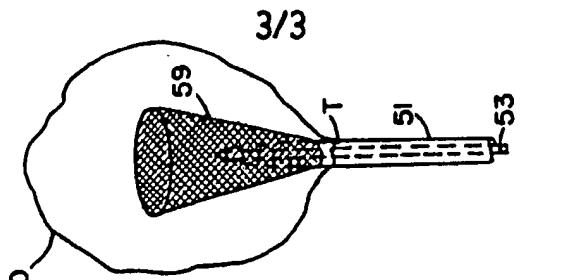


FIG.3A

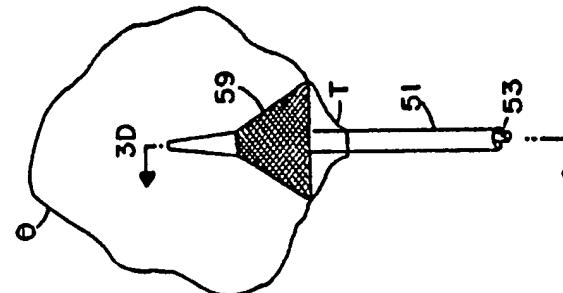


FIG.3B

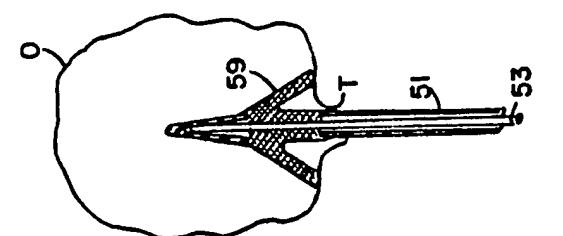


FIG.3C

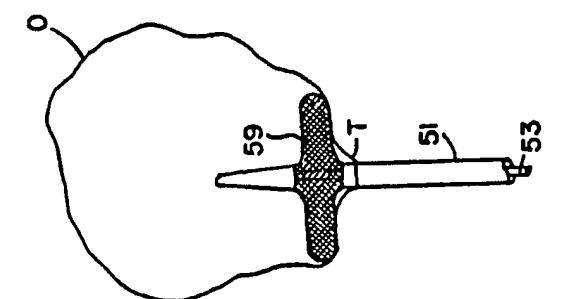


FIG.3D

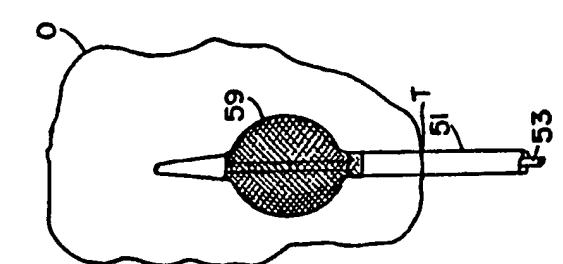


FIG.3E

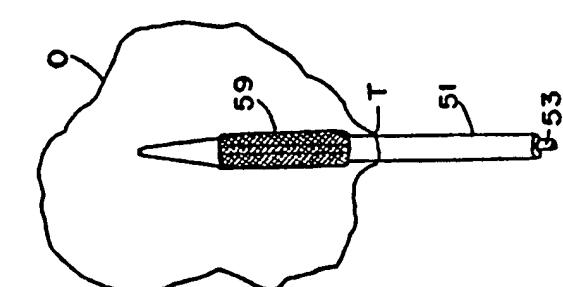


FIG.3F

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# INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/00510

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) According to International Patent Classification (IPC) or to both National Classification and IPC IPC (5): A61M 5/00 U.S.C.L.: 604/104		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched Classification System      Classification Symbols		
U.S.	604/95, 96, 104, 105, 107, 280, 281 606/198	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category	Citation of Document, i.e. with indication, where appropriate, of the relevant passages	Relevant to Cls - No.
X	DT, A, 1,234,923 (KNICHEL) 23 February 1967 See figure	15, 16
X	US, A, 3,996,938 (CLARK III) 14 December 1976 See figure 1-4 and abstract.	15, 16
Y	US, A, 4,571,241 (CHRISTOPHER) 18 February 1986 See abstract.	23
X	US, A, 4,650,466 (LUTHER) 17 March 1987 See entire document	15, 16
X	US, A, 4,819,751 (SHIMADA ET AL) 11 April 1989 See abstract.	15, 16
X	US, A, 4,885,003 (HILLSTEAD) 05 December 1989 See abstract	15, 16
<b>* Special categories of cited documents:</b> "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search <sup>1</sup>	Date of Mailing of this International Search Report <sup>1</sup>	
11 MARCH 1991	16 APR 1991	
International Searching Authority <sup>1</sup>	Signature of Authorized Officer <sup>1</sup> <i>Ralph Lewis</i> RALPH LEWIS	
ISA/US		